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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,770	01/16/2001	Fei Yang	DEX-0113	8352
26259	7590	06/16/2004	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,770

Applicant(s)

YANG ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> . |

DETAILED ACTION

RE: Yang *et al*
Priority Date: 21 May 1998

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/22/2004 has been entered.
2. Claims 2-5 are canceled without prejudice or disclaimer. Claim 8 is newly added.
3. Claims 1, and 6-8 are pending.

Election/Restrictions

4. It is noted that the applicant has amended the claims to include a method requiring the use of polynucleotides and amino acids, of which are patentable distinct inventions. In view of this amendment, a new restriction requirement is set forth herein.
5. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1,6, and 7, drawn to a method for detecting the presence of lung cancer comprising measuring levels of polynucleotides comprising SEQ ID Nos: 2-6 from a patient and comparing the levels of the polynucleotides obtained from the patient to controls, classified in class 435, subclasses 5,6, or class 436, subclass 94.

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- II. Claims 1 and 8, drawn to a method for detecting the presence of lung cancer comprising measuring levels of polypeptides comprising SEQ ID Nos: 7-9 from a patient and comparing the levels of the polypeptides obtained from the patient to controls, classified in class 435, subclass 5,7.1, or class 436, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

6. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ one from the other because the methods require the measuring of two structurally and functionally distinct molecules. Moreover, the method require the use of two different components, namely nucleic acid molecules and amino acids.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. During a telephone conversation with Kathleen Tyrrell on 6/2/2004 a provisional election was made with traverse to prosecute the invention of group I, claims 1,6, and 7. Affirmation of this election must be made by applicant in replying to this Office action. Claim 8 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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9. Therefore, claims 1,6, and 7 are examined on the merits. The claims will be read to the extent that the claims read on polynucleotides only.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

11. Claim 1 is objected to because of the following informalities: the claims make reference to amino acids, which is an invention withdrawn from prosecution as being drawn to non-elected subject matter. Appropriate correction is required.

New Arguments

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1,6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bandman *et al.* The claims are drawn to a method of detecting the presence of lung cancer in a patient comprising measuring the levels of a polynucleotide comprising SEQ ID No: 2-6, and comparing the levels of polynucleotide in the patient with levels in a sample obtained from a control, wherein the polynucleotide levels from the patient are at least two time higher than the levels of the control sample.

Bandman *et al* teach a sequence which is identical to that of SEQ ID No: 3 (see sequence comparison) and further teach a method of detecting the polynucleotide of SEQ ID No: 3 for the purposes of detecting or diagnosing cancer (see col. 33, lines 47-67), wherein the cancer is lung cancer (see col. 34, line 24-62). Bandman *et al* also further disclose the comparison of the experimental samples obtained from a patient and comparing the levels against normal controls (see col. 35 lines 1-26).

Bandman *et al* however do not specifically teach that the levels of the polynucleotide have to be at least two times higher than the control sample. However, this is an obvious variation of the reference teaching absent a showing of unobvious property. It has been held that where the general conditions of a claim are disclosed in

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the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to detect the presence of lung cancer comprising measuring SEQ ID No: 3 in a patient and comparing the levels of SEQ ID No: 3 with those of a control sample, wherein the sample derived from the patient is at least two times higher than the control sample thereby indicating the presence of cancer. One of skill in the art would have been motivated to detect the presence of cancer because Bandman *et al* has already taught a sequence that is identical to SEQ ID No: 3 and has further taught a method of detecting or diagnosing lung cancer using the sequence of SEQ ID No: 3 as the probe. The new limitation of “at least two times higher” does not remedy nor make unobvious the teachings because, Bandman *et al* specifically teach that “[w]ith respect to cancer, the presence of a relatively higher amount of transcript in biopsied tissue from an individual may indicate a predisposition for the development of the disease or may provide a means for detecting the disease prior to the appearance of the actual clinical symptoms” (see col. 35, lines 34-38). One of skill in the art would expect a reasonable amount of success in determining “at least two times higher” amount of transcripts to be indicative of lung cancer because bandman *et al* have already taught that a “higher amount of transcript” would be indicative of a disease state. Therefore claims 1, 6 and are rejected under 35 USC 103(a).

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All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 3/22/2004.


Conclusion

No claim is allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
June 2, 2004


GARY NICKOL
PRIMARY EXAMINER

ALIGNMENTS

RESULT 1

U5-09-008-271A-16

; Sequence 16, Application U5/09008271A
; Patent &0. 6203979
; GENERAL INFORMATION:
; APPLICANT: Bandman, Olga
; Hillman, Jennifer L.
; Yue, Henry
; Guegler, Karl J.
; Corley, Neil C.
; Tang, Tom Y.
; Shah, Purvi
; TITLE OF INVENTION: HDNAN PROTEASE MOLECULES
; NUMBER OF SEQUENCES: 24
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Incyte Pharmaceuticals, Inc.
; STREET: 3174 Porter Dr.
; CITY: Palo Alto
; STATE: CA
; COUNTRY: USA
; ZIP: 94304
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Diskette
; COMPUTER: IBM Compatible
; OPERATING SYSTEM: DOS
; SOFTWARE: FaStSEQ for Windows Version 2.0
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/09/008,271A
; FILING DATE: 16-Jan-1998
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER: <unknown>
; FILING DATE: Kunknown>
; ATTORNEY/AGENT INFORMATION:
; NAME: Mohan-Peterson/ Sheela
; REGISTRATION NUMBER: 41,201
; REFERENCE/DOCKET NUMBER: PF-0458 US
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: 650-855-0555
; TELEFAX: 650-845-4166
; INFORMATION FOR SEQ ID NO: 16:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 2061 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
; IMMEDIATE SOURCE:
; LIBRARY: LUNGASTOI
; CLONE: 877617
; SEQUENCE DESCRIPTION: SEQ ID NO: 16
U5-09-008-271A-16

